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EXAMINER	
GWARTNEY, ELIZABETH A	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/585,019	WITTORFF, HELLE	
	Examiner	Art Unit	
	Elizabeth Gwartney	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-32 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 20090212;20090126;20080922;20071010;20070816;20061113;20060726;20060629.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 2, 7, 14, 16-17, 19, 30 and 32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 2, the phrase "substantially solely" renders the claim indefinite because it is unclear if the gum base contains only “at least one biodegradable polymer”. Further, it is unclear what quantity of “at least one biodegradable polymer” is encompassed by the phrase "substantially solely.

Regarding claim 7, the recitation “wherein the size of the gum base granules are within the range of 0.01 mm · 0.01 mm to 2 mm · 2 mm" renders the claim indefinite because it is unclear what the symbol “·” signifies or whether the recited particle size represents the diameter of particle or another particle size property.

Regarding claim 14, the recitation “wherein the gum base is substantially free of lubricants, anti-adherents and glidants” renders the claim indefinite because it is not clear if the gum base comprises some quantity or none of the recited compounds.

Regarding claims 16-17, the term “substantially” renders the claim indefinite because it is not clear if the gum base comprises wax or fat.

Claim 19 recites the limitation "the chewing gum forming granules" in lines 4-5. There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 30, the recitation "wherein the water content is substantially 0%" renders the claim indefinite because it is not clear if the gum base comprises water or not.

Regarding claim 32, the recitation "conventional non-biodegradable gum base granules" renders the claim indefinite because it is unclear what gum base properties or characteristics are encompassed by the term "conventional."

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-2, 4-5, 7-29 and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thorengaard et al. (WO 2004/004480) in view of Wittorff et al. (WO 02/076230).

Regarding claims 1-2, 4-5, 8-10 and 24-25, Thorengaard et al. disclose gum base granules comprising at least one elastomer in an amount of about 3% to about 35% by weight of

the gum base (p.2/L7-8) wherein the gum base has a water content of less than 1.5% by weight of the gum base (p.5/L19-20). Thorengaard et al. also disclose that the granulated gum base comprises at least one high molecular weight elastomer in an amount of about 3% to about 15% by weight.

Thorengaard et al. fails to disclose at least one biodegradable polymer.

Wittorff et al. teach a degradable gum base comprising elastomer replacement compounds wherein the compounds are biodegradable polyester polymers obtainable by the polymerization of two or more different cyclic ester monomers (Abstract, p.4/Summary of Invention). Wittorff et al. teach that the polyester polymers have a number average molecular weight in the range of 10,000-125,000 g/mol (p.9/L1-6). Wittorff et al. also teach a gum base comprising a degradable co-polymer and a terpolymer (p.6/L29-32).

Thorengaard et al. and Wittorff et al. are combinable because they are concerned with the same field of endeavor, namely, gum base compositions. It would have been obvious to one of ordinary skill in the art at the time of the invention to have used a polyester polymer, as taught by Wittorff et al., to replace elastomeric components (i.e. about 3% to about 35%) in the gum base composition disclosed by Thorengaard et al for the purpose of making a degradable chewing gum product.

Regarding claim 7, modified Thorengaard et al. disclose all of the claim limitations as set forth above. While Thorengaard et al. disclose granulating gum base by means of well-known techniques (p.19/L28-29), the reference does not disclose that the size of the granules are within the range of 0.01 to 2 mm. As the flowability of the granule mixture is a variable that can be modified, among others, by adjusting the size of the gum base granules, the precise granule size

would have been considered a result effective variable by one of ordinary skill in the art at the time of the invention. As such, without showing unexpected results, the claimed granule size cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine techniques, the granule size of the gum base granules of modified Thorengaard et al. to obtain the desired product flowability (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Regarding claims 11-12, modified Thorengaard et al. disclose all of the claim limitations as set forth above. Thorengaard et al. also disclose that the gum base granules comprise at least one low molecular weight elastomer in an amount of about 0% to 25% wherein the molecular weight of said at least one low molecular weight elastomer is from about 1000 g/mol to 50000 g/mol Mn (p.5/L10-15).

Regarding claim 13, modified Thorengaard et al. disclose all of the claim limitations as set forth above. Thorengaard et al. also disclose that the gum base granules comprise additive including sweeteners (p.13/L24-26, p.20/L1-6). While Thorengaard et al. discloses sweeteners, the reference does not explicitly disclose that the sweetener is in an amount of less than 50% by weight. As sweetness is a variable that can be modified, among others, by adjusting the amount of sweetener, the precise amount of sweetener would have been considered a result effective variable by one of ordinary skill in the art at the time of the invention. As such, without showing unexpected results, the claimed amount of sweetener cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by

routine techniques, the amount of sweetener in the gum base granules of modified Thorengaard et al. to obtain the desired sweetness intensity (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Regarding claims 14 and 16-18, modified Thorengaard et al. disclose all of the claim limitations as set forth above. Further, Thorengaard et al. disclose that the gum base granules are free of lubricants, anti-adherents, glidants, wax, and fat and comprise filler in an amount of about 0% to about 50% by weight of the gum base (p.5/L28-29, p.6/L7, 14, 22-23).

Regarding claim 15, modified Thorengaard et al. disclose all of the claim limitations as set forth above. Thorengaard et al. also disclose that the gum base granules comprise natural resins that provide an improved and sticky texture of the gum base when applied in chewing gum formulations (p.6/L4-5).

Regarding claim 19, modified Thorengaard et al. disclose all of the claim limitations as set forth above. Thorengaard et al. also disclose that the gum base granules comprise active ingredients that are added prior to the compression of the final tablet, i.e. blended with pre-mixed gum granules (p.24/L17-24).

Regarding claims 20-22, modified Thorengaard et al. disclose all of the claim limitations as set forth above. Thorengaard et al. also disclose that the gum base granules comprise synthetic resin in an amount of about 1.5% to about 35% by weight (p. 12/L20-21), emulsifiers and/or fats in an amount of about 0.1% to about 35% by weight (p. 12/L29-30), and wax in an amount of about 0.5% to about 30% by weight (p.13/L1-2).

Regarding claim 23, modified Thorengaard et al. disclose all of the claim limitations as set forth above. Thorengaard et al. also disclose that the gum base granules comprise flavoring agents that have been mixed into the chewing gum forming gum base granules previous to compression (p.13/L4-6).

Regarding claim 26, modified Thorengaard et al. disclose all of the claim limitations as set forth above. Thorengaard et al. also disclose a compressed gum comprising gum base granules (Abstract, p.13/L15-17).

Regarding claim 27, modified Thorengaard et al. disclose all of the claim limitations as set forth above. Thorengaard et al. also disclose non-biodegradable polymers, i.e. polyvinyl acetate (PVA) (p.3/L16-20).

Regarding claim 28, modified Thorengaard et al. disclose all of the claim limitations as set forth above. Thorengaard et al. also disclose that the gum granules are blended with chewing gum additives including sweeteners, flavoring agents, fillers, and emulsifiers (p.20/L8-14) and compressed into chewing gum tablets (p. 31/L24-25).

Regarding claim 29, modified Thorengaard et al. disclose all of the claim limitations as set forth above. Thorengaard et al. also disclose that the gum base has a water content of less than 1.5% by weight (p.5/L19-20)

Regarding claim 31, modified Thorengaard et al. disclose all of the claim limitations as set forth above. Wittorff et al. also teach a gum base that comprises at least two biodegradable polymers (p. 6/L28-32).

Regarding claim 32, modified Thorengaard et al. disclose all of the claim limitations as set forth above. Given Thorengaard et al. disclose non-biodegradable gum base granules, since

modified Thorengaard et al. teach biodegradable gum base granules, it would have been obvious to one of ordinary skill in the art at the time of the invention to have combined both types of granules to make a compressed chewing gum with a desired level of degradability.

6. Claims 1-3, 5-18 and 20-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bunczek et al. (US 6,017,566) in view of Gmunder et al. (US 6,200,608).

Regarding claim 1-3, 5-8 and 24-25, Bunczek et al. disclose a gum base comprising approximately 1 to about 80% by weight biodegradable polymer, i.e. polyester, produced through reaction of at least one alcohol and at least one acid including carboxylic acids (C1/L53-62, C2/L45-46, C3/L23, C4/L42-43)) and about 20 to about 60% by weight synthetic elastomer (i.e. non-biodegradable polymer - C10/L45-48).

Bunczek et al. do not disclose gum base granules or that the gum base has a water content of less than 1.0% by weight.

Gmunder et al. teach a particulated chewing gum base (Abstract, C2/L12-18). Gmunder et al. teach that there are reduced processing, preparation and packaging costs associated with making a particulated chewing gum base compared to the conventional method (C13/L4-10). Gmunder et al. teach that a particulated gum base can be easily metered by automatic feeders (C13/L10-12). Further, Gmunder et al. teach that the gum base ingredients are particles 0.6 mm or less (C6/L13-18) and the gum base is free of liquid ingredients (C2/L36-37).

Bunczek et al. and Gmunder et al. are combinable because they are concerned with the same field of endeavor, namely, gum base compositions. It would have been obvious to one of ordinary skill in the art at the time of the invention to have particulated (i.e. granulated), the

chewing gum base of Bunczek et al., as taught by Gmunder et al., for the purpose of reducing processing, preparation and packaging costs and allowing the use of automatic feeders .

Given that Gmunder teach particulating a gum base that is free of liquid ingredients, it is clear that the gum base would intrinsically have a moisture content of less than 1%.

Regarding claims 9-10, modified Bunczek et al. disclose all of the claim limitations as set forth above. Given that Bunczek et al. does not disclose at least one high molecular weight elastomeric biodegradable polymer, it is clear that the amount of high molecular weight elastomeric biodegradable polymer in the gum base would intrinsically be 0%. Further, given Bunczek et al. disclose 0% of a high molecular weight elastomeric biodegradable polymer, it is clear that the limitations of claim 10 are met.

Regarding claims 11-12, modified Bunczek et al. disclose all of the claim limitations as set forth above. Bunczek et al. also disclose that the gum base comprises about 20 to about 60 wt % of a synthetic elastomer including polyvinyl acetate having a weight average molecular weight of about 2,000 to 90,000 g (C10/L45-60).

Regarding claim 13, modified Bunczek et al. disclose all of the claim limitations as set forth above. Given Bunczek et al. does not disclose that the gum base comprises sweetener, it is clear that the gum base comprises sweetener in an amount of less than 50% by weight.

Regarding claim 14, modified Bunczek et al. disclose all of the claim limitations as set forth above. Given Bunczek et al. do not disclose a gum base comprising lubricants, anti-adherents and glidants the limitation of claim 14 is met (see C10/L45-61, C9/Base Examples 8-13).

Regarding claim 15, modified Bunczek et al. disclose all of the claim limitations as set forth above. Bunczek et al. also discloses that the gum base comprises natural rosin ester, i.e. natural resins (C11/L16-17). Given Bunczek et al. disclose a gum base comprising natural resins, it is clear that the natural resins would intrinsically provide an improved and sticky texture of the gum base when applied in chewing gum formulations.

Regarding claims 16-18, modified Bunczek et al. disclose all of the claim limitations as set forth above. Bunczek et al. also disclose that the gum does not include wax (C11/43-45), or fat (C7/Base Example 1-4, C9/Base Example 8-11) and comprises about 4 to about 35 wt% filler (C10/L45-53).

Regarding claim 20, modified Bunczek et al. disclose all of the claim limitations as set forth above. Bunczek et al. also discloses that the gum base comprises about 5 to about 55% by weight elastomer plasticizer, i.e. synthetic resin, including terpene resins (C10/L49-50, C11/L23-25).

Regarding claim 21, modified Bunczek et al. disclose all of the claim limitations as set forth above. Bunczek et al. also disclose that the gum base comprises from about 5 to about 35% by weight softener (i.e. tallow, hydrogenated tallow hydrogenated and partially hydrogenated vegetable oil, cocoa butter - C10/L50-51, C11/L33-36).

Regarding claim 22, modified Bunczek et al. disclose all of the claim limitations as set forth above. While Bunczek et al. disclose that the gum base may comprise wax (C11/L42-45), the reference does not disclose that it is in an amount of about 2% to about 30% by weight of the gum base. As chewiness is a variable that can be modified, among others, by adjusting the amount of wax in the gum base, the precise amount of wax would have been considered a result

effective variable by one of ordinary skill in the art at the time of the invention. As such, without showing unexpected results, the claimed amount of wax cannot be considered critical. Accordingly, one of ordinary skill in the art at the time the invention was made would have optimized, by routine techniques, the amount of wax in the gum base granules of modified Bunczek et al. to obtain the desired chewiness in the resulting chewing gum product (*In re Boesch*, 617 F.2d. 272, 205 USPQ 215 (CCPA 1980)), since it has been held that where the general conditions of the claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. (*In re Aller*, 105 USPQ 223).

Regarding claim 23, modified Bunczek et al. disclose all of the claim limitations as set forth above. Bunczek et al. also discloses mixing flavoring agents into the gum base prior to forming into a chewing gum (C7/Gum Examples 5-7, C9-10/Gum Examples 14-18).

Regarding claim 26, modified Bunczek et al. disclose all of the claim limitations as set forth above. Bunczek et al. also disclose rolled, extruded or casted (i.e. compressed) chewing gum comprising gum base (C12/L55-65).

Regarding claim 27, modified Bunczek et al. disclose all of the claim limitations as set forth above. Bunczek et al. also disclose a gum base comprising about 20 to about 60% by weight synthetic elastomer (i.e. non-biodegradable polymer - C10/L45-48) wherein the chewing gum comprises gum base.

Regarding claim 28, modified Bunczek et al. disclose all of the claim limitations as set forth above. Bunczek et al. also disclose that the gum base is mixed and formed together with ingredients including sweeteners, flavorings, fillers, and emulsifiers (C11/L46-52, C12/L55-61).

Regarding claims 29-30, modified Bunczek et al. disclose all of the claim limitations as set forth above. Given that Gmunder teach particulating a gum base that is free of liquid ingredients (C2/L36-37), it is clear that the gum base would intrinsically have a moisture content of less than 1% or substantially 0%.

Regarding claim 31, modified Bunczek et al. disclose all of the claim limitations as set forth above. Bunczek et al. also disclose that the gum base comprises two biodegradable polymers (C9/Base Examples 8).

Regarding claim 32, modified Bunczek et al. disclose all of the claim limitations as set forth above. While modified Bunczek et al. disclose biodegradable gum base granules in a formed chewing gum, the references do not disclose wherein said biodegradable gum base granules are used together with conventional non-biodegradable gum base granules.

Given Gmunder et al. teach non-biodegradable gum base granules, since modified Bunczek et al. disclose biodegradable gum base granules, it would have been obvious to one of ordinary skill in the art at the time of the invention to have combined both types of granules to make a chewing gum with a desired level of degradability.

7. Claims 1, 4 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wittorff et al. (WO 02/076230) in view of Gmunder et al. (US 6,200,608).

Regarding claim 1, Wittorff et al. disclose a gum base comprising a biodegradable polyester polymer obtainable by the polymerization of cyclic ester monomers (Abstract, p.4/L13-15).

Wittorff et al. do not disclose gum base granules or that the gum base has a water content of less than 5.0% by weight.

Gmunder et al. teach a particulated chewing gum base (Abstract, C2/L12-18). Gmunder et al. teach that there are reduced processing, preparation and packaging costs associated with making a particulated chewing gum base compared to the conventional method (C13/L4-10). Gmunder et al. teach that a particulated gum base can be easily metered by automatic feeders (C13/L10-12). Further, Gmunder et al. teach that the gum base ingredients are particles 0.6 mm or less (C6/L13-18) and the gum base is free of liquid ingredients (C2/L36-37).

Wittorff et al. and Gmunder et al. are combinable because they are concerned with the same field of endeavor, namely, gum base compositions. It would have been obvious to one of ordinary skill in the art at the time of the invention to have particulated (i.e. granulated), the chewing gum base of Wittorff et al., as taught by Gmunder et al., for the purpose of reducing processing, preparation and packaging costs and allowing the use of automatic feeders .

Given that Gmunder teach particulating a gum base that is free of liquid ingredients, it is clear that the gum base would intrinsically have a moisture content of less than 5%.

Regarding claim 19, modified Wittorff et al. disclose all of the claim limitations as set forth above. Wittorff et al. also disclose a composition of chewing gum base which is admixed with chewing gum additives including pharmaceutically or biologically active substances (p.16/L8-15, p.20/L9-10).

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Gwartney whose telephone number is (571) 270-3874. The examiner can normally be reached on Monday - Friday;7:30AM - 3:30PM EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. G./
Examiner, Art Unit 1794

/KEITH D. HENDRICKS/
Supervisory Patent Examiner, Art Unit 1794